COXDUO

Solution for Injection

20 mg Meloxicam

ROUTE OF ADMINISTRATION AND DOSAGE

CATTLE

Antibiotic treatment or in combination with oral rehydration treatment; 0.5 mg/meloxicam/kg body weight **(2.5 ml/100 kg body weight)** a single dose **subcutaneous (s.c.)** or **intravenous (i.v.)** injection.

After dehorning operation **in calves** 0.5 mg meloxicam/kg body weight **(2.5 ml/100 kg body weight) a single dose subcutaneous** or **intravenous injection.**

HORSES

0.6 mg meloxicam/kg body weight **(3 ml/100 kg body weight) a single dose intravenous administration.**

PACK SIZE: 50 - 100 ml

WITHDRAWAL PERIOD

Cattle
Meat: 15 days
Milk: 5 days
(10 milkings)

Shelf Life: **36 months**

COMPOSITION Coxduo 20 mg Solution for Injection is a yellow coloured, clear and sterile solution and each ml contains 20 mg meloxicam as active substance and ethanol for preservative purposes as excipient. PHARMACOLOGICAL PROPERTIES: Pharmacodynamic properties: Meloxicam, an oxicam derivative, is a member of the oxicam class of the enolic acid group of non-steroidal anti-inflammatory drugs (NSAIDs). Meloxicam inhibits prostaglandin synthesis and shows anti-inflammatory, antiexudative, analgesic and antipyretic effects. It decreases leucocyte infiltration into the inflamed tissue. Also, it inhibits collagen sourced thrombocyte aggregation in a small amount. Meloxicam also inhibits thromboxane B2 production induced with E.coli endotoxin administration in calves and cattle in lactation period and this situation shows that meloxicam has anti-endotoxic effects. Pharmacokinetic properties: Absorption After a single subcutaneous administration of 0.5 mg/kg meloxicam, Cmax values of 2.1 µg/ml and 2.7 µg/ml were reached after 7.7 hours and 4 hours in young calves and lactating cattle, respectively. After a single intravenous administration of 0.6 mg/kg meloxicam mean residence time was reported as 3.60 ± 0.63 hours in horses. Diffusion More than 98% of meloxicam is bound to plasma proteins. While the highest meloxicam concentrations are detected in liver and kidney, relatively lower concentrations may be detected in skeletal muscle and fat. Metabolism Meloxicam presents mostly in plasma. It is mainly elimination product in milk and bile in cattle, main compound is only in trace amount in urine. Meloxicam is metabolized to alcohol, acid derivatives and various polar metabolites. It was showed that all main metabolites are pharmacologically inactive. Metabolism in horses was not searched. Elimination Half-life elimination of meloxicam in young calves and cattle in lactation period are respectively 26 hours and 17.5 hours. In horses, it is eliminated with 8.5 hours half-life after intravenous injection. 50% of given dose is excreted by urine and rest of the dose is excreted by feces. AREA OF USE/INDICATIONS Cattle; For use in acute respiratory infections with an appropriate antibiotic therapy to reduce clinical signs in cattle. For use in the treatment of diarrhea in combination with oral rehydration therapy to reduce clinical signs in calves over one week and young, non-lactating cattle. For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy. For the relief of post-operative pain following dehorning in calves. Horses; For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders. For the relief of pain associated with equine colic. ROUTE OF ADMINISTRATION AND DOSAGE: Unless otherwise recommended by a veterinarian, Cattle: Antibiotic treatment or in combination with oral rehydration treatment; 0.5 mg/meloxicam/kg body weight (2.5 ml/100 kg body weight) single dose, subcutaneous or intravenous injection. After dehorning operation in calves 0.5 mg/meloxicam/kg body weight (2.5 ml/100 kg body weight) single dose, subcutaneous or intravenous injection. Horse: 0.6 mg meloxicam/kg body weight (3.0 ml/100 kg body weight) single dose, intravenous injection. Avoid of contamination during the use. SPECIAL CLINICAL INFORMATION AND WARNING FOR TARGET SPECIES Treatment of calves with Coxduo 20 mg Solution for Injection administration 20 minutes before dehorning, reduces post-operative pain. Coxduo 20 mg Solution for Injection alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery with an appropriate analgesic is needed. In case of occurring adverse reactions, stop the treatment and consult to a veterinary physician immediately. Due to possible risk of renal toxicity, avoid use in severely dehydrated, hypovolemic or hypotensive animals requiring parenteral rehydration. If the pain cannot be relieved sufficiently when used in colic treatment in horses, the diagnosis should be carefully reassessed as this may indicate the need for surgical intervention. Use during pregnancy and lactation: Cattle: Can be used during pregnancy and lactation. Horses: Do not use in pregnant or lactating mares. ADVERSE EFFECTS In cattle, subcutaneous or intravenous administrations are well tolerated; only a slight transient swelling was observed at the injection site following subcutaneous administration in less than 10% of the cattle treated in clinical studies. In horses, a transient swelling can be seen at the injection site but resolves without intervention. In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically. The frequency of adverse reactions is defined using the following convention: - Very common (minimum 1 in 10 animals displaying adverse reactions during the treatment) - Common (minimum 1 but less than 10 animals in 100 animals) - Uncommon (minimum 1 but less than 10 animals in 1.000 animals) - Rare (minimum 1 but less than 10 animals in 10.000 animals) -Very rare (minimum 1 animal in 10.000 animals, including isolated reports) DRUG INTERACTIONS Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents. WARNINGS ABOUT DRUG RESIDUES IN FOOD Withdrawal period: Cattle bred for meat should not be sent to slaughter during the treatment and 15 days following the last drug administration and horses 5 days. Cow milks should not be presented to human consumption during the treatment and 5 days (10 milkings) following the last drug administration. It should not be used in horses produced milk for human consumption. CONTRAINDICATIONS Do not use in horses less than 6 weeks of age. Do not use in animals with hepatic, cardiac or renal failure and hemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions. Do not use in case of hypersensitivity to the active substance or to any of the excipients. For the treatment of diarrhea in cattle, do not use in animals of less than one week old. Do not use in pregnant mares and in lactating period. SYMPTOMS IN OVERDOSE, PRECAUTIONS AND ANTIDOTE In case of overdose, symptomatic treatment should be initiated. DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. GENERAL WARNINGS Consult a veterinary physician before use and in case of unexpected effect. Keep out of reach of children. SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VETERINARY MEDICINAL PRODUCT TO ANIMALS Accidental self-injection may cause to pain. People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. STORAGE CONDITIONS AND SHELF LIFE Shelf life is 36 months from the manufacturing date when stored at room temperature below 25°C and in original package. Shelf life is 28 days after the first opening when stored at room temperature below 25°C. Do not refrigerate and/or freeze. Avoid of contamination. The stopper can be perforated for maximum 40 times. NATURE AND COMPOSITION OF IMMEDIATE PACKAGING It is presented in 50 ml and 100 ml transparent, Type II glass vials in cardboard box. Vials are covered with red coloured 20 mm rubber stopper and white flip-off cap. TERMS OF SALE Sold only in veterinary clinics and pharmacies by veterinary prescription. MARKETING AUTHORIZATION DATE AND NUMBER: 20.09.2018-028/015 NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER DEVA Holding A.Ş. Halkalı Merkez Mahallesi Basın Ekspres Cad. No:1 Küçükçekmece/Istanbul/TURKEY e-mail: vetas@vetas.com.tr Tel: +90 212 692 92 92 Fax: +90 212 697 34 89 NAME AND ADDRESS OF THE MANUFACTURING SITE DEVA Holding A.Ş. Çerkezköy Organize Sanayi Bölgesi, Karaağaç Mah. Atatürk Cad. No.32 59510 Kapaklı/Tekirdağ/TURKEY Tel: +90 282 735 20 00 Fax: +90 282 758 16 83

EastPharma

Vetaş

DEVA

Please contact our company for more information. **DEVA HOLDİNG A.Ş.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece / İSTANBUL Tel: 0212 692 92 92 Faks: 0212 697 34 89 • www.vetas.com.tr

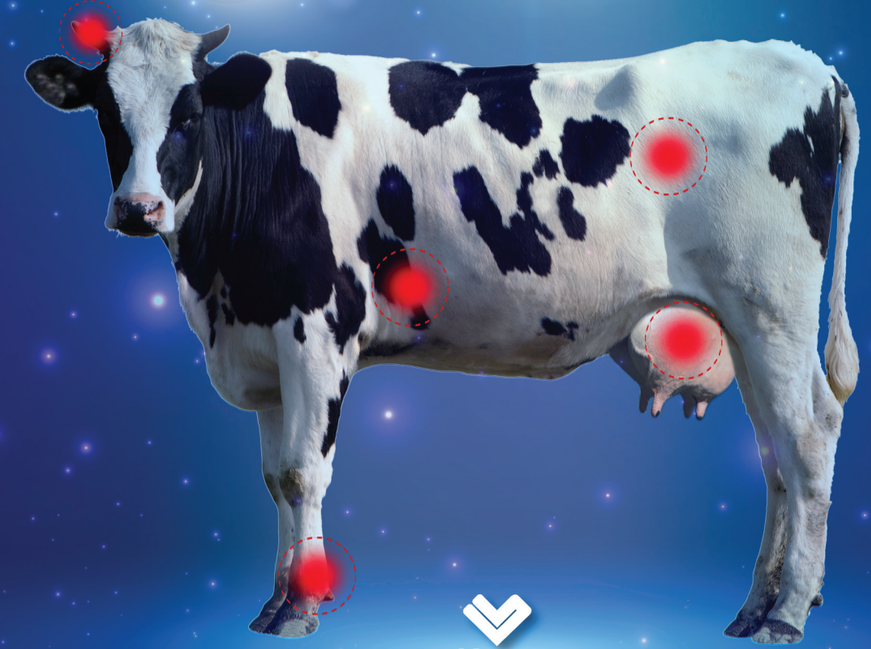
COXDUO

Solution for Injection

20 mg Meloxicam

A deep impression

in pain management



Vetaş

COXDUO

Solution for Injection 20 mg Meloxicam

A deep impression
in pain management

COXDUO 20 mg Solution for Injection is a COX-2 selective NSAID which contains **20 mg Meloxicam** in each ml and has an anti-endotoxic act especially against E.coli endotoxins. A single dose can be administered by I.V and S.C for

- anti-inflammatory
- antiexudative
- analgesic and
- antipyretic

treatment in cattle.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties:

Meloxicam is a member of the oxicam class of the enolic acid group of non-steroidal anti-inflammatory drugs (NSAIDs) which acts by inhibiting prostaglandin synthesis and shows anti-inflammatory, antiexudative, analgesic and antipyretic effects. **Meloxicam is the most selective inhibitor of inducible cyclooxygenase (COX) activity.**

- It decreases leucocyte infiltration into the inflamed tissue.
- It inhibits collagen sourced thrombocyte aggregation in a small amount.
- It inhibits thromboxane B2 production induced with E.coli endotoxin administration in calves and cattle in lactation period and this situation shows that meloxicam has **anti-endotoxic** effects.

Pharmacokinetic properties:

Absorption

After a single subcutaneous administration of 0.5 mg/kg meloxicam, Cmax values of 2.1 µg/ml and 2.7 µg/ml were reached after 7.7 hours and 4 hours in young calves and lactating cattle, respectively.
After a single intravenous administration of 0.6 mg/kg meloxicam mean residence time was reported as 3.60 ± 0.63 hours in horses.

Diffusion

More than 98% of meloxicam is bound to plasma proteins.

Elimination

Half-life elimination of meloxicam in young calves and cattle in lactation period are respectively 26 hours and 17.5 hours.
In horses, it is eliminated with 8.5 hours half-life after intravenous injection.

COX-2

COXDUO

Solution for Injection 20 mg Meloxicam

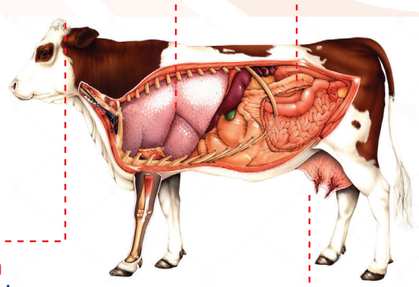
provides a great advantage in treatment with;

- A strong anti-inflammatory and analgesic activity,
- A high concentration in inflamed tissue,
- A low drug interaction,
- A low COX-1/COX-2 rate,
- Less adverse effects.

AREA OF USE

In **acute respiratory tract infections** with an appropriate antibiotic therapy to reduce clinical signs in cattle.

For the relief of **post-operative pain** following dehorning in calves.



In the treatment of **diarrhea** in combination with oral rehydration therapy to reduce clinical signs in **calves over one week** and young, non-lactating cattle

For adjunctive therapy in the treatment of **acute mastitis,** in combination with antibiotic therapy.

HORSES

In the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.
For the relief of pain associated with equine colic.